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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 101/2
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EXAMINER	
SCHLIENTZ, LEAH H	

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte THOMAS E. TARARA and JEFFRY G. WEERS

Appeal 2010-009841
Application 10/750,934
Technology Center 1600

Before TONI R. SCHEINER, LORA M. GREEN, and
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's rejection of claims 38, 39, 41, 44, 47-56, 58, 60, 62-68, 103-105, and 109-111. We have jurisdiction under 35 U.S.C. § 6(b).

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

STATEMENT OF THE CASE

Claim 38 is representative of the claims on appeal, and reads as follows:

38. A pharmaceutical formulation for pulmonary administration, the pharmaceutical formulation comprising:

particulates comprising active agent particles in a matrix comprising a phospholipid, the active agent particles having a geometric diameter of less than about 3 μm and a solubility in water of about 0.1 to about 1.0 mg/ml and wherein the active agent particles are dispersed within the phospholipid matrix; and

wherein the particulates are porous, have a mass median diameter less than 20 μm, a bulk density of less than about 0.5 g/cm^3 a mass median aerodynamic diameter less than about 2.6 μm, and wherein the particulates do not comprise lactose.

The following grounds of rejection are before us for review:

I. Claims 38, 39, 41, 44, 47-56, 58, 60, 62-68, 103-105, and 109-111[2] stand rejected under 35 U.S.C. § 103(a) as being rendered obvious by Weers[3] as evidenced by Weickert,[4] Wiedmann,[5] and Didriksen.[6]

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[2] The Examiner's statement of the rejection refers to claims 38, 39, 41, 44, 47-56, 58, 60, 62-68, and 103-105 (Ans. 4). In the "Grounds of Rejection to be Reviewed on Appeal" Appellants refer to claims 38, 39, 41, 44, 47-56, 58, 60, 62-68, 103-105, and 109-111 (App. Br. 5), and the Examiner states that statement is correct (Ans. 2). We thus consider the Examiner's omission of claims 109-111 to be a typographical error.

[3] Weers et al., WO 01/85136 A2, Nov. 15, 2001) (Weers et al. US 2002/0037316 A1, Mar. 28, 2002, is relied upon by the Examiner as an equivalent, and all citations to Weers are to this publication).

[4] Weickert et al., US 2002/0177562 A1, Nov. 28, 2002.

[5] Wiedmann et al., *Drug solubilization in lung surfactant*, 65 J. CONTROLLED RELEASE 43-47 (2000).

[6] Didriksen et al., WO 00/01365, published Jan. 13, 2000.

II. Claims 38, 39, 41, 44, 47-56, 58, 60, 62-68, 103-105, and 109-111[7] stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of copending Application No. 11/187,757.

We affirm.

ISSUE

Has the Examiner established by a preponderance of the evidence that Weers renders obvious a pharmaceutical formulation for pulmonary administration comprising particulates comprising active agent particles in a matrix comprising a phospholipid, wherein the particulates do not comprise lactose?

FINDINGS OF FACT

FF1 The Examiner's statement of the obviousness rejection may be found at pages 3-9 of the Answer.

FF2 Specifically, the Examiner cites Example V of Weers as exemplifying a water-insoluble drug (Ans. 4).

FF3 The Examiner notes that Example V incorporates lactose into the particulates (*id.* at 7), but notes that lactose is but one of a list of excipients taught by Weers (*id.* at 11 (citing Weers, ¶¶39 and 40)).

FF4 Specifically, Weers teaches that "it may be desirable to add other excipients to a particulate composition to improve particle rigidity,

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[7] See footnote 2.

production yield, emitted dose and deposition, shelf-life and patient acceptance" (Weers, ¶39).

FF5 Weers teaches that other excipients include, but are not limited to, among other things, "disaccharides such as lactose, maltose, sucrose, trehalose, and the like" (*id.* at ¶40).

PRINCIPLES OF LAW

The Supreme Court has emphasized that "the [obviousness] analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR Int'l v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *Id.* at 416. Moreover, an "[e]xpress suggestion to substitute one equivalent for another need not be present to render such substitution obvious." *In re Fout*, 675 F.2d 297, 301 (CCPA 1982).

ANALYSIS

Appellants argue that the only example of Weers that is drawn to particles of an active agent in a phospholipid matrix is Example V, but in that Example budesonide is combined with lactose (App. Br. 6). Claim 38, however, Appellants assert, excludes lactose containing particles (*id.* at 6-7). Appellants argue further that while the Examiner "contends that it would have been obvious to one of ordinary skill in the art to use something other

than lactose in the particulates of Example V," the Examiner has provided "no evidence for this allegedly-obvious modification" (Reply Br. 5).

As to Weickert, Wiedmann, and Didriksen, Appellants argue that they were not relied upon, nor do they make up the deficiencies of Weers (App. Br. 7).

Appellants' arguments have been carefully considered, but are not convincing. As noted by the Examiner, Weers teaches that lactose is but one of a list of different excipients that may be used in the particulate compositions, and other excipients include other disaccharides, such as maltose, sucrose, etc. (FF5). Thus, we agree with the Examiner that it would have been obvious and well within the level of skill of the ordinary artisan to use another excipient as taught by Weers, such as maltose or sucrose, for the lactose in formulating the particulates of Example V of Weers.

As to independent claims 54 and 104, Appellants reiterate the arguments made with respect to independent claim 38 (App. Br. 8-10). Those arguments are not found to be convincing for the reasons set forth with respect to claim 38.

CONCLUSIONS OF LAW

We conclude that the Examiner has established by a preponderance of the evidence that Weers renders obvious a pharmaceutical formulation for pulmonary administration comprising particulates comprising active agent particles in a matrix comprising a phospholipid, wherein the particulates do not comprise lactose. We thus affirm claims 38, 39, 41, 44, 47-56, 58, 60,

62-68, 103-105, and 109-111 under 35 U.S.C. § 103(a) as being rendered obvious by Weers as evidenced by Weickert, Wiedmann, and Didriksen.

As to the obviousness-type double patenting rejection, Appellants only argue that they "will file terminal disclaimers as appropriate upon the indication of otherwise allowable claims" (App. Br. 10). As Appellants are not arguing the merits of the rejection, we summarily affirm the rejection of claims 38, 39, 41, 44, 47-56, 58, 60, 62-68, 103-105, and 109-111 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of copending Application No. 11/187,757.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

cdc

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